(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 908 141 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
09.04.2003 Bulletin 2003/15

(51) Int Cl.[7]: **A61B 17/04**

(21) Application number: **98307204.2**

(22) Date of filing: **07.09.1998**

(54) **A needle holder to assist in suturing**

Chirurgischer Nadelhalter als Hilfsvorrichtung beim Nähen

Porte-aiguille pour faciliter la suture

(84) Designated Contracting States:
DE ES FR GB IT NL

(30) Priority: **08.10.1997 US 946820**

(43) Date of publication of application:
14.04.1999 Bulletin 1999/15

(73) Proprietor: **ETHICON ENDO-SURGERY, INC.**
Cincinnati, Ohio 45242 (US)

(72) Inventors:
- **Swayze, Jeffrey S.**
  Cincinnati, Ohio 45249 (US)
- **Knodel, Bryan D.**
  Flagstaff, Arizona 86002 (US)
- **Nobis, Rudolph H.**
  Mason, Ohio 45040 (US)
- **Yoon, InBae**
  Phoenix, Maryland 21131 (US)

(74) Representative: **Mercer, Christopher Paul**
Carpmaels & Ransford
43, Bloomsbury Square
London WC1A 2RA (GB)

(56) References cited:
EP-A- 0 705 569
DE-U- 9 404 458
FR-A- 337 579
US-A- 2 363 334
US-A- 5 389 103
US-A- 5 674 230
US-A- 5 735 862

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

EP 0 908 141 B1

Printed by Jouve, 75001 PARIS (FR)

Description

Field of the Invention

[0001] The present invention relates to the field of medicine and more particularly to surgery. More specifically, the present invention relates to surgical devices and methods for suturing bodily tissues both for open surgical procedures and for endoscopic surgical procedures. The present invention especially relates to surgical devices and methods for joining hollow organs, e.g. the anastomosis of the small or large intestines, and blood vessels, for joining them together in end-to-end, end-to-side, or side-to-side fashion.

Background of the Invention

[0002] It is common surgical practice to use bypass grafts to help reestablish coronary artery circulation when a portion of the coronary artery is stenosed. Such a procedure is typically referred to as a Coronary Artery Bypass Graft (CABG) procedure. Typically the graft vessel used in bypassing the stenosed portion of the coronary artery comprises one or more segments of the patient's saphenous vein which is taken from his leg. The saphenous vein is dissected free from the leg, its side branches tied off or ligated, and the vein removed. The vein graft is then washed free of blood, and cut into portions of suitable length. Each portion is then passed to the surgeon who trims the ends of the graft before anastomosing the graft to the aorta and the coronary artery. Other graft vessels such as the radial artery in the arm can also be used. In addition, it is common practice today for the surgeon to redirect one of the internal mammary arteries (IMA) in the chest to the stenosed portion of the left anterior descending (LAD) artery on the heart. The end of the IMA near the patient's diaphragm is transected, the artery is mobilized by dissection and ligation of side branches, and then the end is joined to the LAD, just distal to the blockage. For multiple bypass surgery, a combination of the redirection of the IMA and the grafting of vessels to the diseased coronary arteries is often used.

[0003] Some surgeons choose to complete all the proximal anastomoses to the aorta before commencing the distal anastomoses to the coronary arteries. In contrast, others choose to complete the distal anastomoses first. Regardless of the order, when undertaking the distal anastomoses to the coronary artery, it is important that the vessel graft be held steady and adjacent the coronary artery, with a minimum of vascular trauma and a minimum of visual and surgical obstruction by instruments in the narrow operative field.

[0004] The speed of performing such anastomoses can become extremely critical as well. Often the coronary artery is occluded during the procedure so that the anastomoses can be performed more easily. It is very important to reconnect the supply of blood to artery as soon as possible in order to minimize or prevent damage to the patient. Blood vessels are now normally anastomosed end-to-end or end-to-side by suturing techniques. Conventionally, to suture two vessels together, a surgeon passes the pointed tip of a curved suturing needle, having a suture attached to the blunt end, through the coronary artery wall from inside the lumen. The needle is then passed through the graft vessel wall from the outside. Then, the surgeon grasps the tip of the needle which has been forced through the tissues with fingers or a needle holder and pulls the needle through the tissues, the suture following the curved path of the needle. Usually a knot or button is present at the trailing end of the suture to anchor the first stitch. After the surgeon has pulled the suture entirely through the tissues to tension the first stitch, he or she then forces the tip of the needle through the coronary artery again, at a location spaced from the first stitch, until the needle again goes through the coronary artery and back out through the graft vessel. Again, he grasps the tip of the needle which has been forced through the tissues, applies tension to the needle pulls the entire suture through the tissues to complete the second stitch. This process is repeated again and again, with the surgeon tensioning the suture after each stitch to draw the tissues together thereby creating a running or continuous stitch, composed of individual thread loops, which extends around the graft vessel.

[0005] Needless to say, such suturing techniques are a tedious and time consuming task. Suture anastomoses procedures generally take the skilled surgeon anywhere from ten to twenty minutes to complete for each anastomoses. An example of a device which was designed to help a physician in performing suturing can be found in U.S. Patents 5,437,681 issued to Meade et al. on August 1, 1995 and 5,540,705 issued to Meade et al. on July 30, 1996, both of which are hereby incorporated herein by reference. However, there are a number of disadvantages to the device disclosed in those references. In those devices it is the device itself which drives the needle through the tissue. Many physicians do not like this design because they like to have more control of needle placement and feel the resistance of the needle passing through the tissue when doing the procedure. Surgeons want the speed and efficacy offered by the new devices, but also want to maintain the benefits of the traditional suturing techniques.

[0006] Further devices designed to help a physician are disclosed in FR 337 579, EP 0 705 569 and US-A-2 601 564. The last of these discloses a device having the features of the preamble of claim 1 appended hereto.

[0007] Presently, there are no known simple, yet foolproof, devices for helping the physician perform the anastomoses more quickly and with greater precision than when using conventional instruments. The present invention provides a device and method which overcomes the shortcomings of the prior art and helps the

physician to suture bodily tissues easily and quickly with a single instrument. It is especially useful for performing an easy and quick vascular anastomoses such as for a CABG procedure.

Summary of the Invention

[0008] In accordance with the present invention there is provided a device for assisting a physician in suture procedures, wherein the physician is using a needle and a suture attached thereto. The device includes a handle for holding the device.

[0009] Extending distally from the handle are a pair of arms, right and left. The arms have proximal ends attached to the handle. The distal ends of the arms have grippers attached thereto, for gripping and releasing a needle. The device includes at least one means for moving the distal ends of the arms closely adjacent to one another so as to pass the needle from one gripper to the other. Thereafter, the device is able to move the distal ends of the arms further apart from one another, without any substantial movement of the needle with respect to the handle.

[0010] In accordance with another aspect of the present invention, the above described device has right and left arms wherein the distal ends of those arms comprise curved sections which extend laterally and distally away from the proximal ends of the arms. The device would then include a mechanism for rotating the arms so as to move the distal ends of the arms closely adjacent to one another so as to pass the needle from one gripper to the other. Thereafter, the device would again rotate at least one arm so as to move the distal ends of the arms away from each other.

Brief Description of the Drawings

[0011] The foregoing and other aspects of the present invention will best be appreciated with reference to the detailed description of the invention in conjunction with the accompanying drawings, wherein:

Figures 1-10 depict the sequence of operation of the present invention;

Figure 1 is a perspective view of the present invention showing a curved, surgical needle being placed into the distal end of the device while the loading button is being depressed;

Figure 2 is an enlarged, partial view of the device depicted in Figure 1, with the trigger and handle top removed for clarity;

Figure 3 is a perspective view of the present invention and shows the curved, surgical needle held in the distal end of the device after the loading button has been released, and a portion of the handle top and bottom has been cut away to view the barrel;

Figure 4 is an enlarged, partial view of the device depicted in Figure 3, but with the trigger and handle top removed for clarity;

Figure 5 is a perspective view of the present invention, showing the curved, surgical needle held in the distal end of the right arm and the distal end of the left arm swung laterally apart from the right arm after the trigger has been actuated to the down position;

Figure 6 is an enlarged, partial view of the device depicted in Figure 5, but with the trigger and handle top removed for clarity;

Figure 7 is a perspective view of the present invention showing the curved, surgical needle held in the distal end of both the right and left arms after the trigger has been released to the up position;

Figure 8 is an enlarged, partial view of the device depicted in Figure 7, but with the trigger and handle top removed for clarity;

Figure 9 is a perspective view of the present invention showing the curved , surgical needle held in the distal end of the left arm while the distal end of the right arm has been swung laterally apart from the left after the trigger has been actuated to the down position;

Figure 10 is an enlarged, partial view of the device depicted in Figure 9, but with the trigger and handle top removed for clarity;

Figures 11A, 11B, 11C, 11D, and 11E are distal end views of the present invention depicting the sequence shown in Figures 3, 5, 7, 9 and 3 again, respectively;

Figures 12A, 12B, 12C, and 12D are alternate views of Figures 2 and 4, 6, 8, and 10, respectively;

Figures 13A, 13B, 13C, and 13D are cut-away views of Figures 12A, 12B, 12C, and 12D, respectively;

Figures 14A, 14B, and 14C are perspective views of the barrel for the clockwise, center, and counterclockwise positions, respectively;

Figure 15 is a enlarged, perspective view of the barrel depicted in Figure 14B, but with the barrel cover removed for clarity;

Figure 16 is a perspective view of the barrel depicted in Figure 14B, but with the barrel cover and yoke

removed for clarity;

Figures 17A, 17B, and 17C are alternate views of the barrel depicted in Figures 14A, 14B, and 14C, respectively, with the barrel cover and yoke removed for clarity, and looking from the proximal end;

Figure 18 is a perspective view of a curved, surgical needle in the distal end of the present invention as depicted in Figure 5;

Figure 19 is a perspective view of a curved, surgical needle in the distal end of the present invention in the configuration corresponding to Figure 20A;

Figures 20A and 20B are top, cross-sectional views of the barrel as depicted in Figures 14A and 14B;

Figure 21 is a side, cross-sectional view of the barrel together with the loading button in the up position as depicted in Figure 2 for the present invention;

Figure 22 is a side, cross-sectional view of the barrel together with the loading button in the down or actuated position and corresponds to the present invention as depicted in Figure 1;

Figure 23 is an exploded, perspective view of all the components of the present invention; and

Figure 24 shows perspective views of the present invention as it may be held by a surgeon and depicting a method for its use.

[0012] The drawings are not necessarily to scale.

Detailed Description of the Invention

[0013] The suturing device of the present invention can be used to suture any type of anatomical tissue which may also be sutured using the traditional surgical methods described earlier. The device described herein is for use through any sufficiently-sized incision into the body, such as a mini-thoracotomy, but may also be used on external portions of the body such as for plastic surgery. It should also be clear to one of ordinary skill in the art that the present invention can be configured and provided with sealing means so as to make it possible to use through an endoscopic port. The device described herein is shown being used with a surgical needle having a particular radius of curvature. It may also be used with needles having other curvature radii or of many other shapes and sizes, including ski-shaped and straight needles, depending on the surgeon's preference for the surgical procedure being performed.

[0014] Referring now to the figures wherein like numerals indicate the same elements throughout the views there is shown in Figure 1 a suturing device 5 in accordance with the present invention. Device 5 includes a handle 6 at its proximal end. Handle 6 includes a button 16 and a trigger 17 whose functions will be explained in detail below. Handle 6 is essentially a cylindrical body which is shaped ergonomically so that a surgeon may comfortably grip it and actuate the button 16 and trigger 17 with the same hand. The handle top 39, the handle bottom 18, the trigger 17, and the button 16 can be made of any substantially rigid, medical grade material but is preferably formed of a plastic such as polycarbonate. As will become apparent, this one hand manipulation of the device is advantageous in that it frees the surgeon's other hand for holding the tissue or other instrumentation. The length of the trigger 17 and the general shape of the handle 6 may vary from what is depicted in Figure 1 in order to accommodate particular ergonomic requirements.

[0015] Extending distally from the handle 6 is a left tubular arm 14 and a right tubular arm 15. While the arms 14 and 15 are preferably round tubular, substantial longitudinal portions of them may have other cross-sectional shapes such as rectangular tubular or a C-shaped channel. The distal portions of arms 14 and 15 each have an offset bend section 80, 81 or dogleg so that the longitudinal axis of the distal arm ends 82, 83 are parallel to and offset from the longitudinal axis of the proximal arm ends 84, 85. The distal arm ends 82, 83 may differ from what is shown in that one or both of them may also be slightly angled with respect to the longitudinal axis of the device rather than be parallel to it. For example, both distal arm ends could be equally angled in towards each other. On the distal tip of left arm 14 is left gripper 8 comprising a left gripper head 10 and the left arm flange 12. Similarly, the distal tip of right arm 15 has a right gripper 9 comprising a right gripper head 11 and the right arm flange 13. As will be explained in greater detail below, grippers 8 and 9 are designed to alternately grip and release needle 1, as it is being passed from right arm 15 to left arm 14 and back again. The gripper heads 10, 11 and the arms 14, 15 may be made of a rigid, medical grade material including metal and plastic, but the preferred material is stainless steel.

[0016] The proximal portion of the arms 14, 15 may be exposed as shown in Figures 1, 3 ,5,7 and 9, or may also be covered partially by the handle top 39 and handle bottom 18 as depicted in Figures 23 and 24. The length of the arms 14, 15 may vary considerably without resulting in a change of the function or usage of the device. Both of these variations are limited mostly by the overall rigidity of the device and the ease of manipulating it.

[0017] A brief and simplified description of how the device 5 works can best be accomplished by referring to Figures 11A-11E in conjunction with Figure 1. In Figure 11A the needle has just been loaded into the device so that both grippers 8 and 9 are holding the needle and the trigger it is in its up position (the trigger is explained in greater detail below). Thereafter, trigger 17 is pressed

down and left gripper 8 releases the needle and swings away from the distal end of arm 15 as shown in Figure 11B. The arc length of this swing motion is the same for each full actuation. However, it is possible to vary the design of the mechanisms later described so that this arc length can be significantly more or less than what is shown in Figure 11B. The needle 1 can now be inserted into tissue and brought back out again by the surgeon's own action of twisting his wrists or the like. (This method of suturing using the present invention is depicted in Figure 24.) Now right gripper 9 is on the side of the needle insertion site and left gripper 8 is on the side of the needle exit site. Therefore, the trigger is now released to its up position again so that left gripper 8 can grip the needle again as shown in Figure 11C. As the trigger is pressed down this time, it is the right gripper 9 which releases the needle and is swung away from the left gripper 8 as shown in Figure 11D. The arc length of this motion may be designed also to vary significantly as described for the other gripper. In this position the surgeon can now move the needle away from the tissue, pulling the suture therethrough so as to complete a stitch. Once this is done the trigger is again released so that gripper 9 grips the needle again and the process can be repeated. As will become apparent, the proximal arm ends 84, 85 never translate laterally with respect to each other. The swinging back and forth action of the left and right grippers is accomplished by axially rotating the arms 14, 15, causing the offset bend sections 80, 81 to move with respect to the handle 6.

[0018] The detail of how the above sequence of operation is accomplished by device 5 can best be described by referring to Figures 1, 3, 5, 7 and 9. Each of these figures has a corresponding illustration, Figures 2, 4, 6, 8 and 10 respectively, showing an enlarged portion of the mechanism in the handle 6 which controls the opening and closing of the grippers 8 , 9 and the rotation of the arms 14, 15. Hereinafter, the needle will be described as being passed from the right gripper 9 to the left gripper 8 and then back to the right gripper 9, but it is also possible for the needle point to be directed in the opposite lateral direction, in which case the needle would be passed from the left gripper 8 to the right gripper 9 and then back to the left gripper 8. It should be noted also that the traditional surgical technique for pitching and catching a needle has been maintained in the present invention, in that a twisting motion of the surgeon's hand to penetrate the tissue with the needle as well as to pull the needle and trailing suture out of the tissue is still required. This is advantageous in that the surgeon still controls the precise placement and manipulation of the needle, yet is able to do so with one device rather than with two as when using traditional suturing techniques.

[0019] Referring to Figure 1, a surgical needle with trailing suture is shown in the position it would be held as it is lowered into the left and right grippers 8 and 9. During this step, the button 16 is depressed by the surgeon, causing both the left and right gripper heads 10, 11 to be displaced distally from the corresponding left and right arm flanges 12, 13, creating a sufficient gap to allow loading of the needle. The actual mechanism for moving the left and right gripper heads will be explained in detail below. As will become apparent to those of ordinary skill in art as they read this description, the button 16 can also be pushed in order to load the needle 1 when the trigger is in the position shown in Figure 7.

[0020] In Figures 1 and 2, the trigger 17 is not yet actuated and is in what is hereinafter referred to as its "up" position. Figure 2 shows an enlarged view of some of the components of the handle and trigger mechanisms, with trigger 17 and handle bottom 39 removed for clarity. Two trigger prongs 36 (partially visible in Figure 1, 3, and 7) project distally from the bottom side of trigger 17. These prongs fit slideably into toggle plate recesses 28 of toggle plate 19. When the trigger is actuated in the downward direction, pivoting about trigger pivot 29, the toggle plate and the trigger distal end move vertically together. The trigger is biased in the "up" position by trigger spring 51 (see Figure 23.) In Figures 1, 2, since the trigger is in the "up" position for this step, the toggle plate 19 is also in the "up" position with respect to handle 6. Handle 6 further includes a toggle 23 which is pivotably attached to the toggle plate 19 and partially resides within a toggle plate rail 27. Toggle 23 has a left toggle surface 24 and a right toggle surface 25 (see Figures 8, 10.) In Figure 4, toggle 23 is shown in its full, clockwise position.

[0021] Handle 6 further includes a toggle switch 20 mounted to handle bottom 18 by toggle switch mount 21. Toggle switch 20 has a tip 22, which is shown in Figure 2 as bearing against right toggle surface 24 and toggle plate rail 27. Toggle switch 20 is attached to switch mount 21, and flexes in the lateral direction. However, it does not move up or down with respect to the handle. It is toggle plate 19 that moves up and down with respect to the handle. In Figure 2, toggle switch 20 is flexed to its right-of-center position. Also partially visible in Figure 2 is cylindrical barrel 30 nested in the bottom handle 18. As will be explained later, it is the rotation of this barrel about its longitudinal axis which causes the movements of the grippers 8, 9, and the arms 14, 15.

[0022] The toggle plate 19 and toggle 23 are preferably made of a rigid, medical grade plastic such as polyetherimide. The toggle switch 20 functions as a leaf spring biased in the central plane position which intersects the pivot 26 of the toggle 23 and is made of a spring material such as a rigid plastic or preferably, stainless steel.

[0023] Referring now to Figure 3, the button 16 has been released so that the left and right gripper heads 10, 11 move proximally under spring force to hold the needle tightly against the left and right arm flanges 12, 13. The position of the left and right grippers as shown is hereinafter referred to as the "home" position. As can be seen, Figures 2 and 4 are identical because the trig-

ger has not been actuated, only button 16 has been deactuated. Therefore, the toggle plate 19, toggle 23, and toggle switch 20 have not changed position.

[0024] Now that the surgeon has loaded the needle into the grippers 8 and 9, device 5 can be further explained by referring to Figure 5. In this figure, the trigger has been pressed down by the surgeon, so that the trigger is now in what is hereinafter referred to as its "down" position. In this figure, the entire device has been rotated slightly about its longitudinal axis for clarity. By placing the trigger in its down position, the needle 1 has been released by left gripper 8 and arm 14 has rotated or spun about its longitudinal axis so that left arm distal end 83 has swung away from the right arm distal end 82. Figure 18 shows a clear, perspective view of the distal portion of the present invention shown in Figure 5. In this view it can be seen that the left gripper 8 has swung away from its home position and is open, thus allowing the surgeon to penetrate the tissue with the needle 1.

[0025] By referring to Figure 6, one can see the movement of the toggle plate 19 and toggle 23. When the trigger is pressed down by the surgeon, the toggle plate 19 moves down within handle bottom 18, carrying toggle 23 with it. As a result, toggle plate rail 27 has moved down and away from toggle switch tip 22, allowing toggle switch 20 to spring laterally to its biased center position.

[0026] At this point in the sequence of operation, the needle is ready to be placed into the tissue using the same surgical technique as when using a conventional needle driver. While the trigger 17 is still being held down, the needle tip is placed against the tissue and the handle 6 is twisted clockwise about its longitudinal axis so that the needle tip penetrates the tissue and exits on the opposite side. This step is depicted in Figure 24.

[0027] After the surgeon has penetrated the tissue he needs to pull the suture all the way through to make a stitch. This is done by returning the trigger to its up position and can best be described by referring to Figure 7. As seen from that figure, the trigger 17 has been released to its up position so that the left gripper 8 has returned to its home position to grasp the needle 1, while right gripper 9 has maintained its grasp of needle 1, much in the way that it did in Figure 3. However, by referring to Figure 8, one can see that the toggle 23 and toggle switch 20 are in different positions than that shown in Figure 4. As seen from this Figure, the toggle plate 19 has again moved upwardly with the trigger 17, carrying with it toggle 23. However, during this movement, toggle switch tip 22 now contacts left toggle surface 24 (see Figure 4), causing toggle 23 to rotate counter clockwise as the trigger 17 is released to the up position.

[0028] The next step of the operational sequence is the actuation of the trigger 17 to its down position again, as shown in Figure 9. This causes the right gripper 9 to release the needle and causes arm 15 to rotate so that its distal end swings away from the left gripper 8. In this configuration, it is now possible for the surgeon to use the device like a conventional needle holder and to pull the needle 1 and its trailing suture (see the third sequence of Figure 24) out of the tissue, thus completing the stitch through tissue. Corresponding Figure 10 shows the movement of the toggle plate 19 to its down position, allowing the toggle switch 20 to spring to its center biased position. The final step of the operational sequence is to release trigger 17 and is done after the distal end of the device is moved away from the tissue in order to allow the return of right gripper 9 to its home position as shown in Figure 3. The toggle plate 19, the toggle 23, and the toggle switch 20 return also to the configuration shown in Figures 3 and 4, and the sequence may be repeated for another stitch into tissue.

[0029] Again, Figures 11A - 11E show an end view of the left and right grippers 8, 9 and the needle 1 for each of the steps of the operational sequence shown in Figures 3, 5, 7, 9 and 3 again, respectively. For each step, the needle 1 is stationary with respect to the device handle 6; it is always one of the grippers 8, 9 which is moving to and from the needle 1.

[0030] Figures 12A, 12B, 12C, and 12D are alternate views of Figures 2, 6, 8, 10, respectively. The toggle plate 19, toggle 23, switch 20, and barrel 30 are shown from the proximal end, and again depict the operational sequence. Note that for each step, barrel 30 remains centered on the X, Y reference frame axes 74, 75. It is the toggle plate 19 and toggle 23 which move vertically, causing toggle switch 20 to deflect laterally to the left or right of its centered position. Barrel 30 rotates either clockwise or counterclockwise due to its interaction with the up and down movement of the toggle plate 19. As will be explained below, rotation of the barrel causes the rotation of the arms 14 and 15 and the simultaneous actuation of grippers 8 and 9. The barrel as shown rotates upon the inside of the handle bottom 18. It should be appreciated that there are various other features that may be designed into the handle and/or onto the barrel in order to provide rotational support for the barrel, and that the embodiment shown is not intended to be limiting.

[0031] As seen from Figures 13A - 13D, when the trigger is first actuated into the down position the barrel rotates clockwise about 90 degrees. When the trigger is released back into the up position, the barrel rotates counter clockwise about 90 degrees, back to its original position. Thereafter, when the trigger is again fired the barrel then rotates counter clockwise about 90 degrees and when released it rotates clockwise back to its original position. Figures 13A, 13B, 13C, and 13D correspond to Figures 12A, 12B, 12C, and 12D, respectively. The rotation of the barrel is accomplished by the fact that the barrel is connected to toggle plate by projection 31 and left and right toggle plate tracks 33, 32. When trigger 17 is actuated, the full clockwise orientation of the toggle 23 allows the barrel projection 31 to traverse the right toggle track 32 (Figure 13B) while the full coun-

terclockwise orientation of the toggle allows the barrel projection 31 to traverse the left toggle track 33 (Figure 13D).

[0032] Figures 14A, 14B, and 14C show the three possible positions of the barrel projection 31 due to the interaction with the toggle plate 19 and the toggle 23 for when the trigger 17 is in the fully upward or fully downward position. Figure 14A shows the full clockwise rotation about the longitudinal axis 62; Figure 14B shows the center or "home" position of the barrel; Figure 14C shows the full counterclockwise position. Partial views of the left arm proximal end 85 and the right arm proximal end 84 entering into the distal end of the barrel 30 are shown. As seen from these figures, the left and right arm proximal ends remain in a constant position with respect to each other. As mentioned before, movement of distal arm ends is caused by the rotation of the arms acting upon the offset bend sections 80, 81.

[0033] Figure 15 corresponds with Figure 14B and is a perspective view of the assembled components inside the barrel 30. Barrel cover 34 has been removed for clarity. Barrel 30 includes a yoke 43, preferably made from a rigid plastic. Cam lid 42 is made from a rigid plastic and fits tightly together with the barrel cover 34 to encapsulate the assembly. Yoke 43 houses a left pinion assembly 52 and a right pinion assembly 53. The following components of the left pinion assembly 52 are individually depicted in the exploded view of Figure 23: a left pinion 44 which is attached to left arm proximal end 85; a left cam head 49 which may be metal or plastic and fits slideably into left pinion 44 and captures left pinion spring 46. Likewise, the right pinion assembly 53 includes a right cam head 50, right pinion spring 47 (not shown in Figure 15), a right pinion 45 (also not shown in Figure 15) and right arm proximal end 84. Figure 16, wherein the yoke has been removed, has been presented to show the left and right pinion assemblies 52, 53 respectively as they interact with the inside of cam lid 42. Cam heads 49, 50 are attached to cables 40, 41, respectively, which are assembled slideably through longitudinal holes in pinions 44, 45.

[0034] Figures 17A, 17B, 17C correspond with Figures 14A, 14B, and 14C, respectively, and show the proximal end of the components shown in Figure 16. These figures are intended to show how the rotation of the barrel 30, and hence cam lid 42 due to their attachment to one another, causes the rotation of the left and right pinion assemblies 52, 53, which in turn causes the arms 14, 15 to rotate in order to swing grippers 8, 9 between their two end positions. In Figure 17A, the cam lid 42 has been rotated to the full clockwise position due to the trigger actuation and the steps described in the preceding paragraphs. This cam lid position corresponds to Figures 5, 6, 12B, and 13B.

[0035] The cam lid gear teeth 54 mesh with the left pinion gear teeth 55 to cause the rotation of the pinion assembly 52 about its longitudinal axis 60 as the trigger is pressed into its down position. The rotation of pinion assembly 52 about its longitudinal axis 60 causes arm 14 to rotate which in turn causes left gripper 8 to swing to the position shown in Figures 5 and 11B. Simultaneously, right pinion sliding surface 58 of the right pinion assembly 53 slides along cam lid sliding surface 59, the right pinion assembly 53 therefore does not rotate about axis 61, and the right gripper 9 stays in its home position. The opposite interaction takes place when the cam lid 42 is caused to rotate counterclockwise as shown in Figure 17C, causing right gripper 9 to swing away from its home position. Figure 17B depicts the home position for both grippers 8, 9 and occurs when the cam lid gear teeth 54 are located in the central position and neither the left pinion gear teeth 55 or the right pinion gear teeth 56 are engaged.

[0036] Before the rotation of the left arm 14 takes place, causing the left gripper 8 to swing away from its home position, it is necessary for the left gripper 8 to release its hold of the needle 1, while the right gripper 9 maintains its grip. (See Figure 19.) This is also true for the when the right arm 15 swings away from its home position, that is, the right gripper 9 must first release the needle 1. The timing for the actuation of grippers 8, 9 is designed accordingly, and is controlled by the cam mechanism within the barrel 30.

[0037] Figures 20A and 20B are longitudinal cross-sectional views of the barrel 30, cam lid 42, and yoke 43, containing the left and right pinion assemblies 52, 53, as configured in Figures 14A and 14C respectively, where the section for each was taken through a plane intersecting main axis 62 and barrel projection 31. Referring first to Figures 20A and 19, left arm proximal end 85 is attached to left pinion assembly 52 and right arm proximal end 84 is attached to right pinion assembly 53. Left and right pinion assemblies 52, 53 are shown in their relative positions within the barrel and are comprised of left and right cam heads 49, 50, and left and right pinion springs 46, 47, respectively. The left cam head 49 is attached to a left cable 40, which runs through the entire length of arm 14 where it is attached at its distal end to left gripper head 10, whereby all three components move together. Likewise, the right cam head 50 is attached to a right cable 41 which is attached to right gripper head 11 so that these three components move together. Compression springs 46 and 47 exert a longitudinal force such that cables 40 and 41 are usually, unless as otherwise noted below, under tension.

[0038] Cables 40, 41 are flexible in order to move easily in the longitudinal direction through the offset of the distal portion of the left and right arms 14, 15 respectively, and may be made of a semi-rigid plastic or of metal wire strands. The cables are constrained in the channels within the arms so that they also can transmit a compressive force sufficient for moving the gripper heads distally.

[0039] In Figures 20A, 20B it can be seen that the barrel 30 has a peripheral cam surface 64 at its proximal end. Cam surface 64 is always in contact with the left

and right cam heads 49 and 50, and the right and left pinion cam surfaces 67, 68 are always in contact with the cam lid peripheral cam surface 66, due to the longitudinally outward force of the left and right pinion springs 46 and 47.

[0040] In Figure 20A the barrel is rotated in the full clockwise position, as also shown in Figures 6, 12B, 13B, 14A, and 17A. The right pinion spring 47 is assembled into the barrel partially compressed and is shown in Figure 20A for when it has its maximum allowable length. The longitudinal force of the spring has caused the right cam head 50 to move proximally, thereby moving cable 41 and right gripper head 9 proximally. Simultaneously, right pinion 53 has moved distally, causing right arm 15 and right arm flange 13 to move distally. These two, opposing movements provide a bi-directional grip on the needle 1. Again in Figure 20A, the left pinion spring 46 is at its minimum allowable length because the left arm 14 was moved in the proximal direction and the left cam head 49 was moved in the distal direction. This results in the bi-directional separation of the left gripper head 10 and the left arm flange 12 as can be seen in Figure 19. This separation feature is advantageous because the needle is centered on the gap between the gripper head 10 and arm flange 12, and therefore allowable variation of needle alignment with the gap is greater than if only the gripper head 10 or the arm flange 12 were to move alone. This feature facilitates "catching" of the needle. Figure 20B shows the opposite configuration to that of Figure 20A and corresponds to Figure 14C for when the barrel 30 is rotated to the full counterclockwise position. The needle is gripped in the left gripper 8 and released by right gripper 9, just prior to right arm 15 swinging away from the home position.

[0041] Now turning to Figures 21 and 22, the operation of the button 16 for the loading and release of needle 1 from the distal end of the present invention is next described. In Figure 21, which corresponds to Figure 3, the needle 1 is gripped by both the left gripper 8 and the right gripper 9, both in the home position, the button 16 is in the full upward or non-actuated position . It is held there by the spring forces exerted by the left and right pinion springs 46, 47 pushing simultaneously against left and right cam heads 49, 50, and against the left and right pinions 44, 45, which in turn impart a longitudinally directed force on the yoke 43 in the distal direction. A yoke ramp surface 73 transmits this force to the button ramp surface 72, forcing the button 16 vertically upwards. In Figure 22 which corresponds to Figure 1 when the needle 1 may be loaded into or released from the grippers 8, 9, the button 16 is pushed downwards by the surgeon, imparting a longitudinal force in the proximal direction onto the yoke 43, which in turn bears against left and right pinions 44, 45, causing them to move in the proximal direction against the spring forces exerted by left and right pinion springs 44, 45, and finally resulting in the movement in the proximal direction of left and right arms 14, 15 which are attached to left and right pinions 44, 45. Thus, the respective gaps between the gripper heads 10, 11 and the arm flanges 12, 13 increase equally to a width greater than the diameter of the needle being used. The interfacing button ramp surface 72 and yoke ramp surface 73 also serve to key the yoke 43 so that it does not rotate when the trigger 17 is actuated and the barrel 30 and cam lid 42 rotate within the stationary handle bottom 18 and handle top 39.

[0042] Although particular embodiments of the present invention have been shown and described, modification may be made to the device without departing from the scope of the present invention as defined by the appended claims.

Claims

1. A device (5) for assisting a physician in suture procedures using a needle and a suture attached thereto, said device (5) comprising:

   a) a handle (6) for holding said device (5), said handle (6) having distal and proximal ends;
   b) right and left arms (14, 15) extending distally from said handle (6), said arms (14, 15) having proximal ends attached to said handle (6) and distal ends having grippers (8, 9) attached thereto for gripping and releasing a needle. the grippers having a gripping state and a releasing state; and
   c) moving means for moving said distal ends of said arms (14, 15) and for passing said needle from one gripper (8, 9) to the other without any substantial axial movement of said needle with respect to the handle (6);

   characterised in that:

   d) the right and left arms define a right shaft axis and a left shaft axis and the arms (14, 15) are rotatable substantially about their shaft axes to move said distal ends;
   e) said moving means comprises a sequencing mechanism comprising a trigger (17), a toggle (23) and a toggle plate (19), the sequencing mechanism being arranged such that:

      (i) in a first state, with the trigger (17) in a released position, both grippers (8,9) are in a gripping state and are closely adjacent one another;
      (ii) as the trigger (17) is pressed, a first (8) of the grippers (8, 9) changes to a releasing state and then rotates away from the second (9) of the grippers (8, 9);
      (iii) as the trigger (17) is released, the first gripper (8) rotates towards the second gripper (9) and then changes to a gripping state;
      (iv) as the trigger is again pressed, the sec-

ond gripper (9) changes to a releasing state and then rotates away from the first gripper (8); and
(v) as the trigger is again released, the second gripper (9) rotates towards the first gripper (8) and then changes to a gripping state to result in the sequencing mechanism resuming its first state.

2. The device according to Claim 1, wherein said trigger (17) is on said handle (6).

3. The device according to Claim 2 and including a needle, wherein in the first state wherein said distal ends of said arms (14, 15) are closely adjacent one another, both of said grippers (8, 9) are engaging said needle, in the second state wherein said distal end of said left arm (14) has been moved away from said distal end of said right arm (15), said first gripper (8) has released its engagement with said needle and in the fourth state wherein the trigger (17) is in a position corresponding to that of the second state, said second gripper (9) has released its engagement with said needle and has been moved away from said distal end of said left arm (14), all these states being reached without any substantial movement of said needle with respect to the handle (5).

4. The device according to any one of Claims 1 to 3, wherein said handle (6) includes a button (16), said button (16) being connected to a means for opening and closing said grippers (8, 9) so as to insert and remove a needle to and from said grippers (8, 9).

5. The device according to any one of the preceding Claims, wherein each gripper (8, 9) comprises a distal gripper head (10, 11) and a proximal flange (12, 13), wherein said gripper head and flange (10, 11, 12, 13) move adjacent one another for gripping a needle and move apart from one another for releasing a needle.

6. The device according to Claim 5, wherein both said gripper head (10, 11) and said flange (12, 13) move with respect to said handle (6) when gripping and releasing a needle.

Patentansprüche

1. Hilfsvorrichtung (5) für einen Arzt bei Nähvorgängen unter Verwendung einer Nadel mit daran angebrachtem Nahtmaterial umfassend:

a) einen Griff (6) zum Halten der Vorrichtung (5), wobei der Griff (6) ein distales und ein proximales Ende aufweist;

b) einen rechten und einen linken Arm (14, 15), die sich in distaler Richtung vom Griff (6) aus erstrecken, wobei diese Arme (14, 15) proximale, am Griff angebrachte Enden und distale, mit Greifern (8, 9) versehene Enden haben, die zum Greifen und zur Freigabe einer Nadel dienen und einen Greifzustand und einen Freigabezustand einnehmen können und

c) eine Bewegungseinrichtung zum Bewegen der distalen Enden der Arme (14, 15) und zum Übergeben der Nadel von einem Greifer (8, 9) zum anderen ohne jegliche wesentliche axiale Bewegung der Nadel in bezug auf den Griff (6); **dadurch gekennzeichnet, daß**

d) der rechte und der linke Arm eine rechte Schaftachse bzw. eine linke Schaftachse definieren und die Arme (14, 15) zur Bewegung der distalen Enden im wesentlichen um ihre Schaftachsen drehbar sind;

e) die Bewegungseinrichtung einen Folgemechanismus mit einem Auslöser (17), einem Antriebsstift (23) und einer Stifteingriffs-Platte (19) umfaßt, welcher derart angeordnet ist, daß:

(i) sich in einem ersten Zustand mit freigegebenem Auslöser beide Greifer (8, 9) in ihrem Greifzustand eng beieinander befinden;

(ii) wenn der Auslöser (17) gedrückt wird, ein erster (8) der Greifer (8, 9) in einen Freigabezustand wechselt und sich dann vom zweiten (9) der Greifer (8, 9) weg dreht;

(iii) wenn der Auslöser (17) freigegeben wird, sich der erste Greifer (8) zum zweiten Greifer (9) hin dreht und dann in einen Greifzustand wechselt;

(iv) wenn der Auslöser (17) wieder gedrückt wird, der zweite Greifer (9) in einen Freigabezustand wechselt und sich dann vom ersten Greifer (8) weg dreht und

(v) wenn der Auslöser (17) wieder freigegeben wird, sich der zweite Greifer (9) zum ersten Greifer (8) hin dreht und dann in einen Greifzustand wechselt mit dem Ergebnis, daß der Folgemechanismus wieder seinen ersten Zustand einnimmt.

2. Vorrichtung nach Anspruch 1, bei welcher sich der Auslöser (17) auf dem Griff (6) befindet.

3. Vorrichtung nach Anspruch 2 mit einer Nadel, bei welcher im ersten Zustand, in welchem sich die distalen Enden der Arme (14, 15) nahe beieinander befinden, beide Greifer (8, 9) an der Nadel anliegen, im zweiten Zustand, in welchem sich das distale Ende des linken Armes (14) vom distalen Ende des rechten Armes (15) weg bewegt hat, der erste Greifer (8) seine Anlage an der Nadel gelöst hat und im vierten Zustand, in welchem sich der Auslöser in einer Position befindet, die derjenigen des zweiten Zustandes entspricht, der zweite Greifer (9) seine Anlage an der Nadel gelöst hat und sich vom distalen Ende des linken Armes (14) weg bewegt hat, wobei alle diese Zustände ohne eine wesentliche Bewegung der Nadel in bezug auf den Griff (5) erreicht werden.

4. Vorrichtung nach einem der Ansprüche 1 bis 3, bei welcher der Griff (6) einen Knopf (16) aufweist und dieser Knopf (16) mit einer Einrichtung zum Öffnen und Schließen der Greifer (8, 9) verbunden ist, um eine Nadel in die Greifer (8, 9) einzusetzen bzw. aus diesen zu entnehmen.

5. Vorrichtung nach einem der bisherigen Ansprüche, bei welcher jeder Greifer (8, 9) einen distalen Greiferkopf (10, 11) und einen proximalen Flansch (12, 13) aufweist, wobei der Greiferkopf und der Flansch (10, 11, 12, 13) sich nahe beieinander bewegen, um eine Nadel zu ergreifen und voneinander weg zu bewegen, um die Nadel freizugeben.

6. Vorrichtung nach Anspruch 5, bei welcher sich sowohl der Greiferkopf (10, 11) als auch der Flansch (12, 13) in bezug auf den Griff (6) bewegen, wenn eine Nadel ergriffen bzw. freigegeben wird.

Revendications

1. Dispositif (5) destiné à aider un médecin dans les procédures de suture utilisant une aiguille et une suture attachée à celle-ci, ledit dispositif (5) comprenant :

   a) une poignée (6) pour saisir ledit dispositif (5), ladite poignée (6) comportant une extrémité distale et une extrémité proximale ;
   b) des branches droite et gauche (14, 15) s'étendant distalement par rapport à ladite poignée (6), lesdites branches (14, 15) possédant des extrémités proximales fixées à ladite poignée (6) et des extrémités distales possédant des dispositifs de préhension (8, 9) fixés à celles-ci pour la préhension et la libération d'une aiguille, les dispositifs de préhension pouvant adopter un état de préhension et un état de relâchement ; et
   c) un mécanisme de déplacement pour déplacer lesdites extrémités distales desdites branches (14, 15) et pour passer ladite aiguille d'un dispositif de préhension (8, 9) à l'autre sans aucun mouvement axial substantiel de ladite aiguille par rapport à la poignée (6) ;

   Caractérisé en ce que :

   d) les branches droite et gauche définissent un axe du corps droit et un axe du corps gauche et les branches (14, 15) sont pivotantes de manière substantielle autour de leurs axes de corps pour déplacer lesdites extrémités distales.
   e) ledit mécanisme de déplacement comprend un mécanisme de séquence comprenant un dispositif de déclenchement (17), une articulation (23) et un support d'articulation (19), le mécanisme de séquence étant disposé de telle sorte que :

      (i) dans un premier état, avec le dispositif de déclenchement (17) dans une position relâchée, les deux dispositifs de préhension (8, 9) sont dans un état de préhension et sont en position étroitement adjacente l'un par rapport à l'autre ;
      (ii) lorsque le dispositif de déclenchement (17) est pressé, le premier (8) des dispositifs de préhension (8, 9) change pour un état de relâchement et s'éloigne par rotation du second (9) des dispositifs de préhension (8, 9) ;
      (iii) lorsque le dispositif de déclenchement (17) est relâché, le premier dispositif de préhension (8) tourne en direction du second dispositif de préhension (9), et change pour un état de préhension ;
      (iv) lorsque le dispositif de déclenchement est à nouveau pressé, le second dispositif de préhension (9) change pour un état de relâchement et s'éloigne par rotation du premier dispositif de préhension (8) ; et
      (v) lorsque le dispositif de déclenchement est à nouveau relâché, le second dispositif de préhension (9) tourne en direction du premier dispositif de préhension (8) et change pour un état de préhension avec pour conséquence que le mécanisme de séquence reprend son premier état.

2. Dispositif selon la revendication 1, dans lequel ledit dispositif de déclenchement (17) est sur ladite poignée (6).

3. Dispositif selon la revendication 2 et incluant une aiguille, dans lequel, dans le premier état dans lequel les extrémités distales desdites branches (14, 15) sont étroitement adjacentes l'une à l'autre, les

deux dispositifs de préhension (8, 9) enclenchent ladite aiguille, dans le second état dans lequel ladite extrémité distale de ladite branche gauche (14) s'est éloignée de ladite extrémité distale de ladite branche droite (15), ledit premier dispositif de préhension (8) a libéré son enclenchement avec ladite aiguille et dans le quatrième état dans lequel le dispositif de déclenchement (17) est dans une position correspondant à celle du second état, ledit second dispositif de préhension (9) a libéré son enclenchement de ladite aiguille et s'est éloigné de ladite extrémité distale de ladite branche gauche (14), tous ces états étant atteint sans aucun mouvement substantiel de ladite aiguille par rapport à la poignée (6).

4. Dispositif selon l'une quelconque des revendications 1 à 3, dans lequel ladite poignée (6) comprend un bouton (16), ledit bouton (16) étant connecté à un dispositif d'ouverture et de fermeture desdits dispositifs de préhension (8, 9) afin d'insérer et de retirer une aiguille dans et à partir desdits dispositifs de préhension (8, 9).

5. Dispositif selon l'une quelconque des revendications précédentes, dans lequel chaque dispositif de préhension (8, 9) comprend une tête de préhension distale (10, 11) et une collerette proximale (12, 13), dans lequel lesdites tête de préhension et collerette (10, 11, 12, 13) se déplacent en position adjacente l'une par rapport à l'autre pour saisir une aiguille et s'éloignent l'une par rapport à l'autre pour relâcher une aiguille.

6. Dispositif selon la revendication 5, dans lequel ladite tête de préhension (10, 11) et ladite collerette (12, 13) se déplacent par rapport à ladite poignée (6) lors de la préhension et du relâchement d'une aiguille.

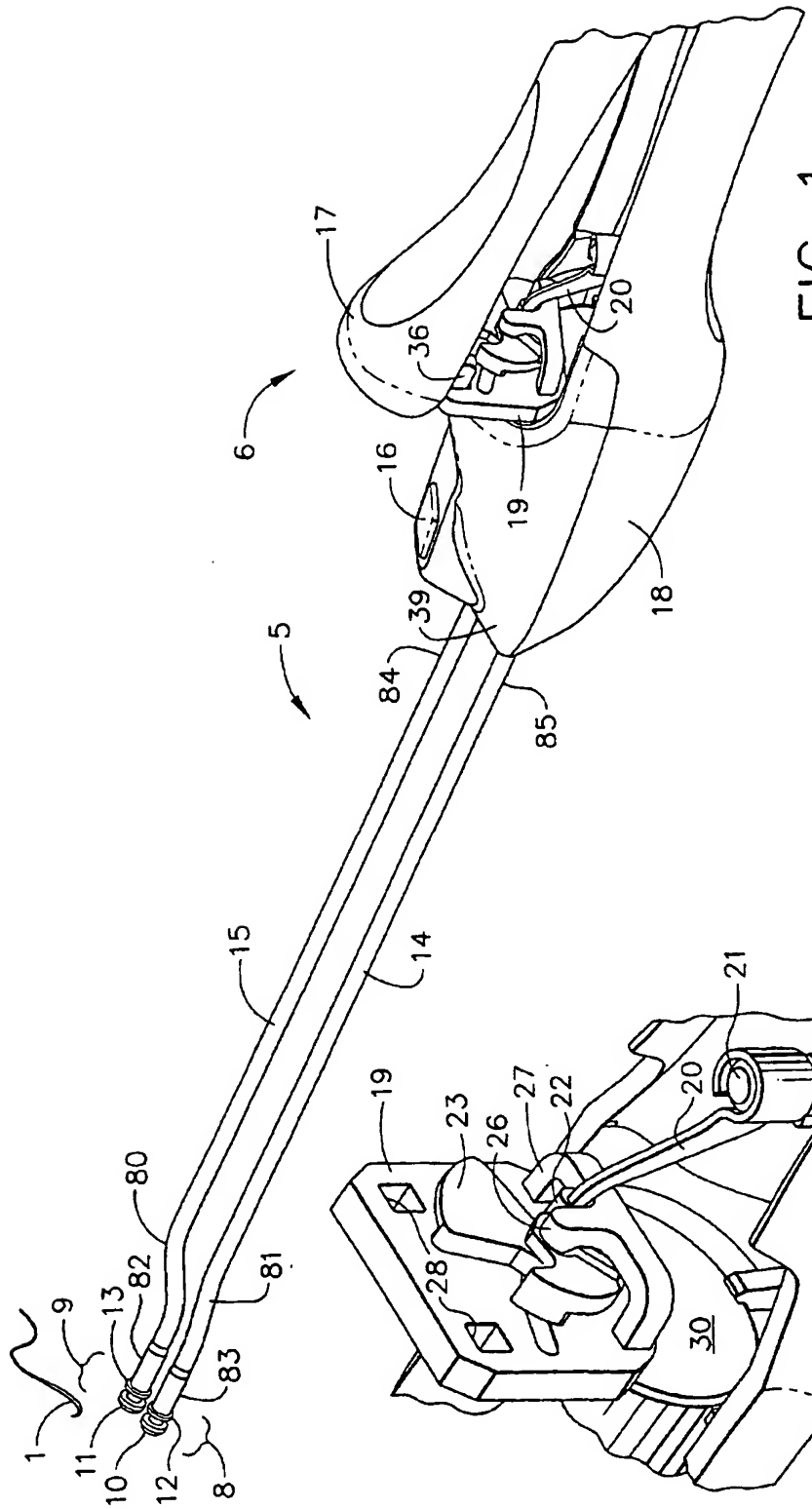
17
36
20
6
16
19
18
39
5
84
85
15
14
80
82
81
13
9
83
1
11
10
12
8

FIG. 1

21
19
23
26
27
22
20
28
30
18

FIG. 2

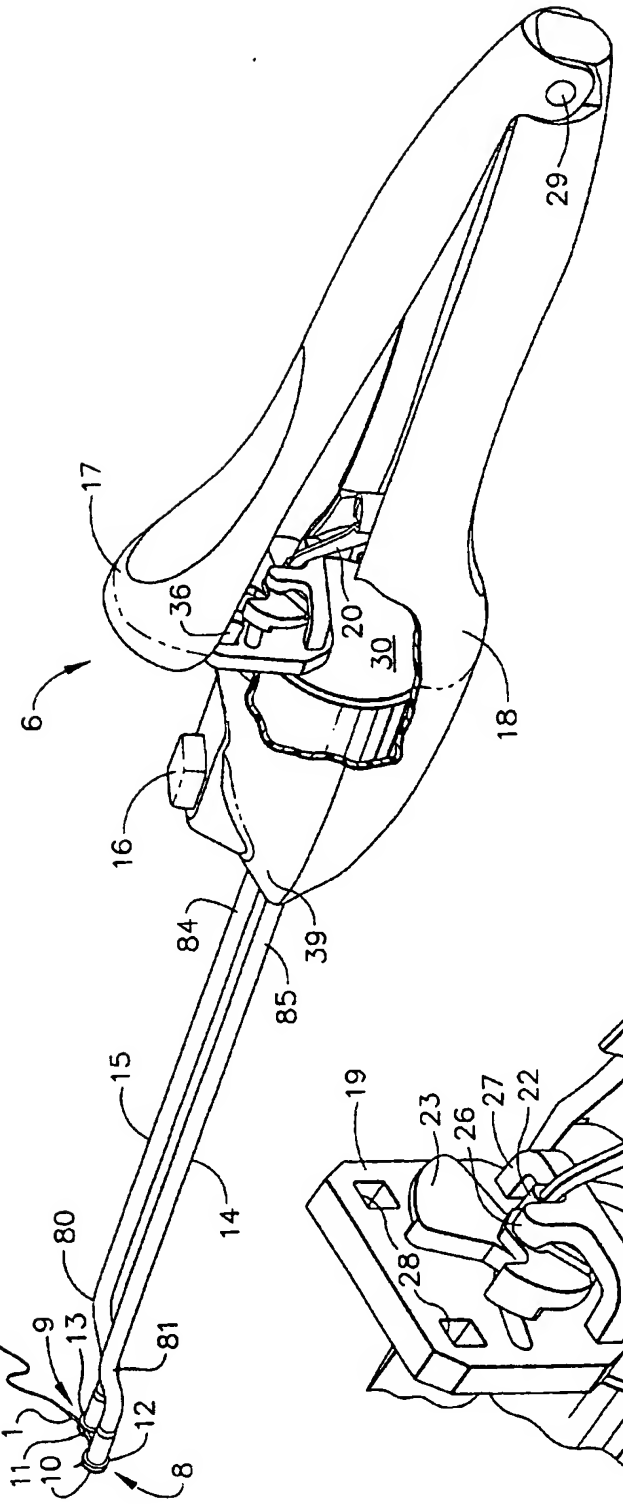
29
17
36
20
30
6
18
16
84
39
85
15
14
80
9
13
81
12
1
11
10
8

FIG. 3

21
19
23
26
27
22
20
28
30
18

FIG. 4

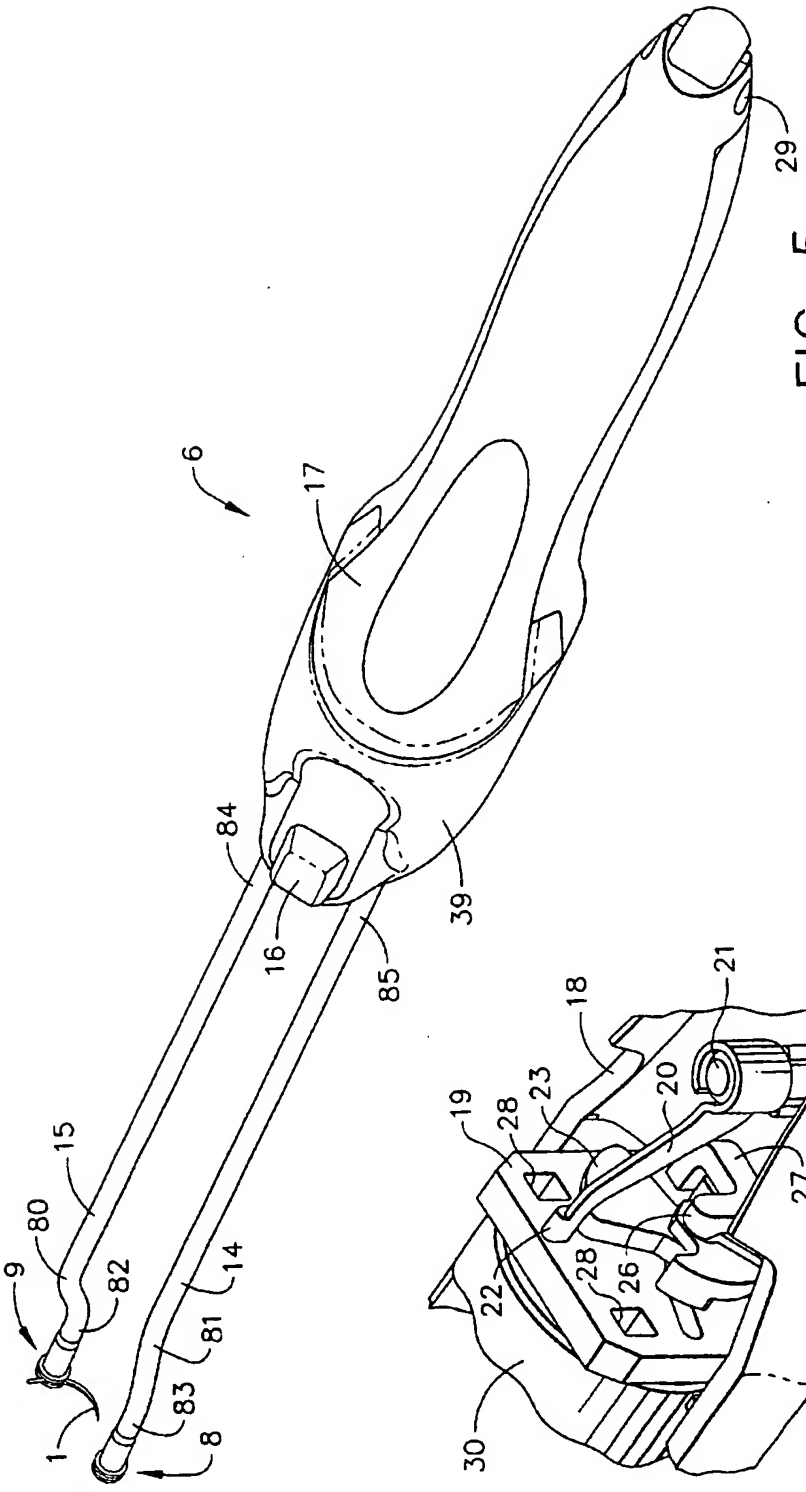
6
17
29
84
16
85
39
9
80
15
82
14
81
83
1
8

FIG. 5

18
21
19
28
23
20
27
22
28
26
30

FIG. 6

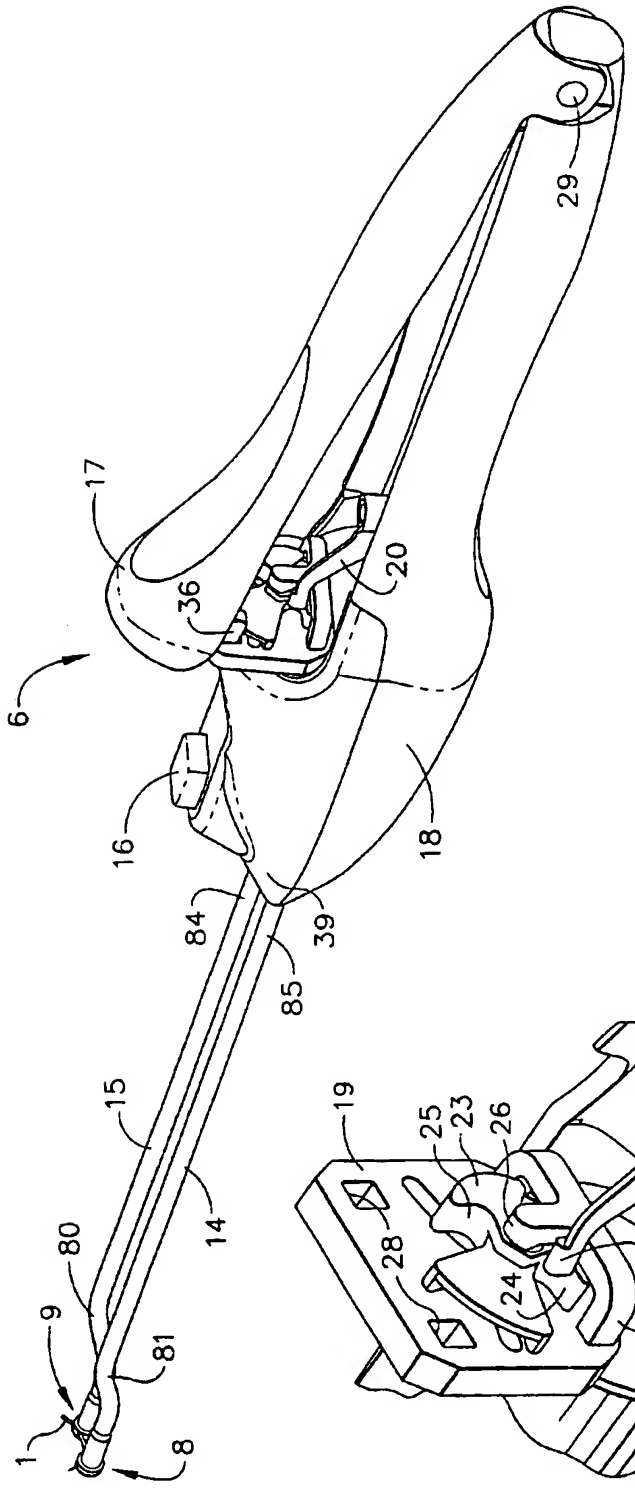
29
17
36
20
6
16
18
84
39
85
15
14
80
9
81
1
8

FIG. 7

21
19
25
23
26
20
28
24
22
27
30
18

FIG. 8

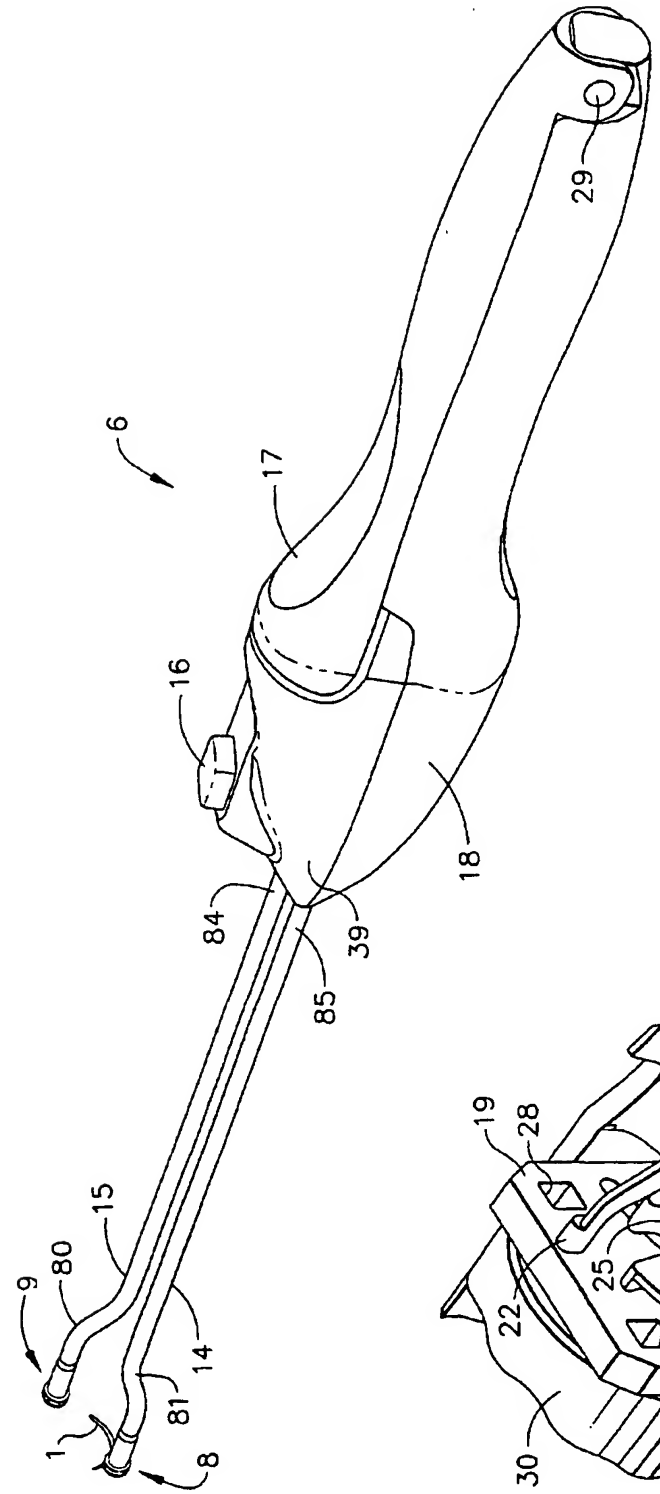
6
17
29
16
18
84
39
85
15
80
9
14
81
1
8

FIG. 9

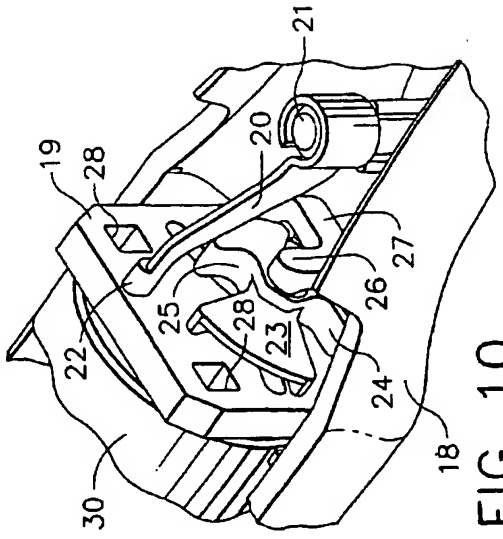
21
20
19
28
27
26
25
28
23
22
24
18
30

FIG. 10

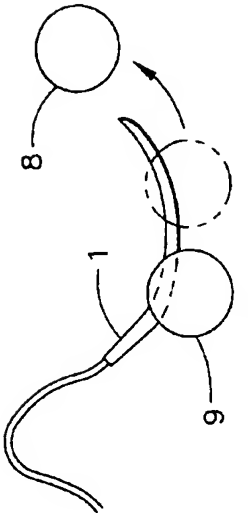

FIG. 11B

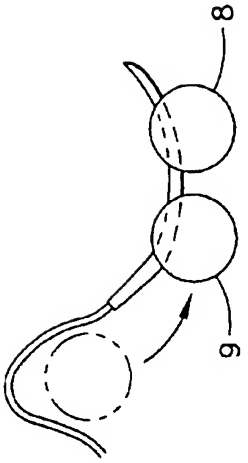

FIG. 11E

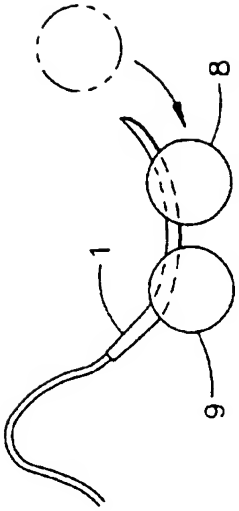

FIG. 11C

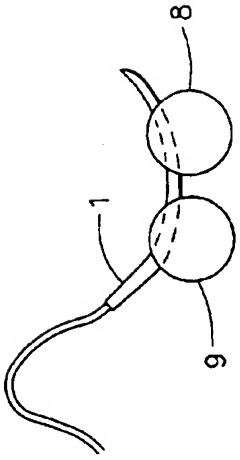

FIG. 11A

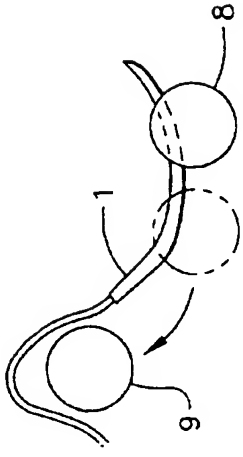

FIG. 11D

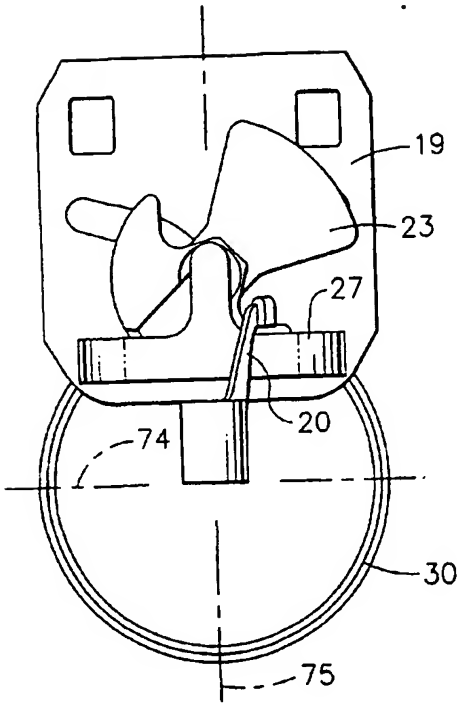

FIG. 12A

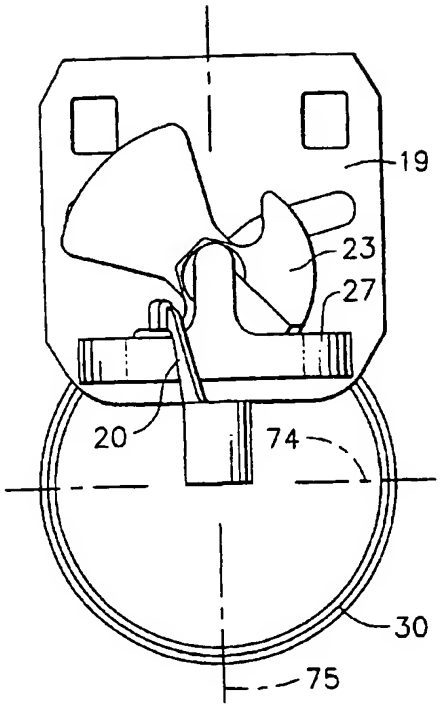

FIG. 12C

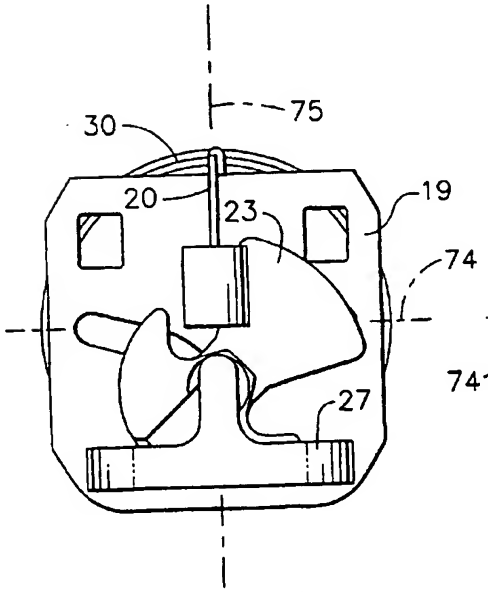

FIG. 12B

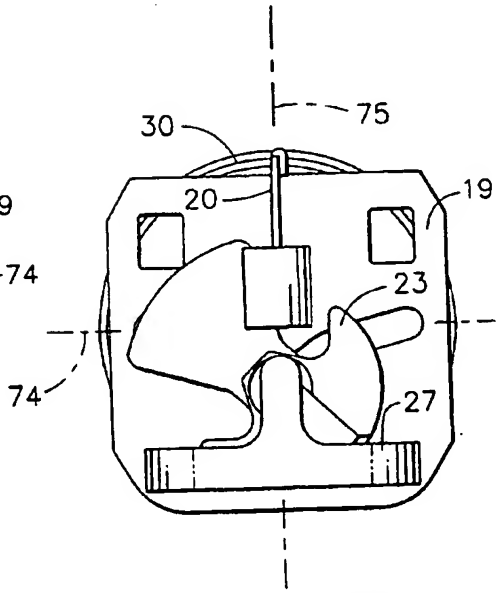

FIG. 12D

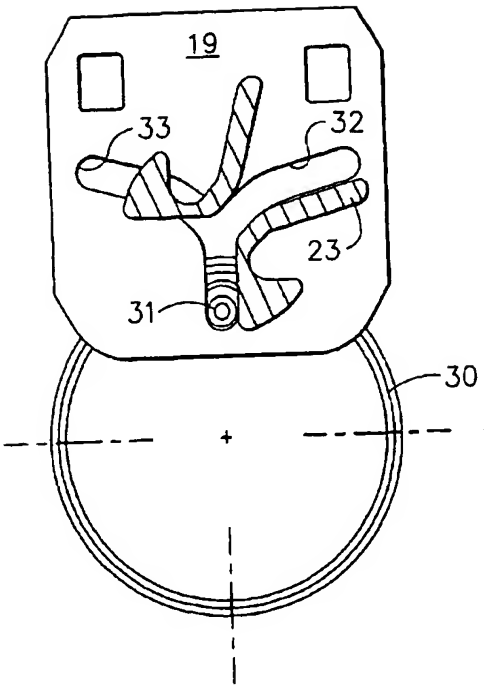

FIG. 13A

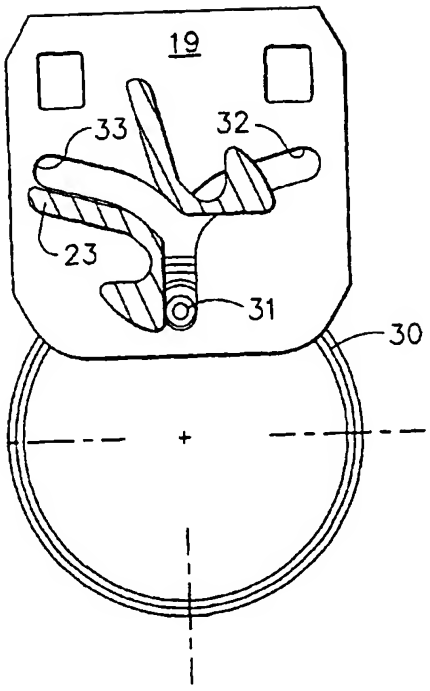

FIG. 13C

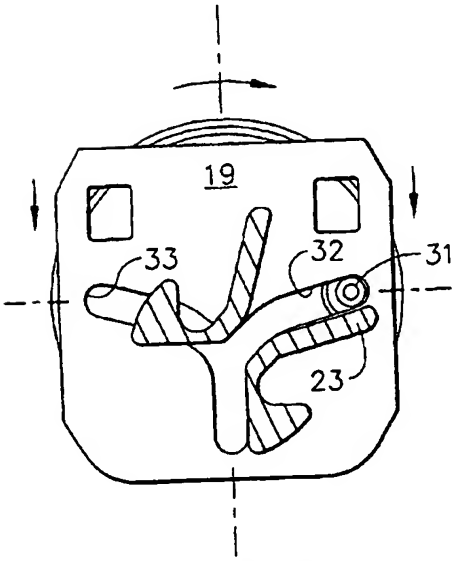

FIG. 13B

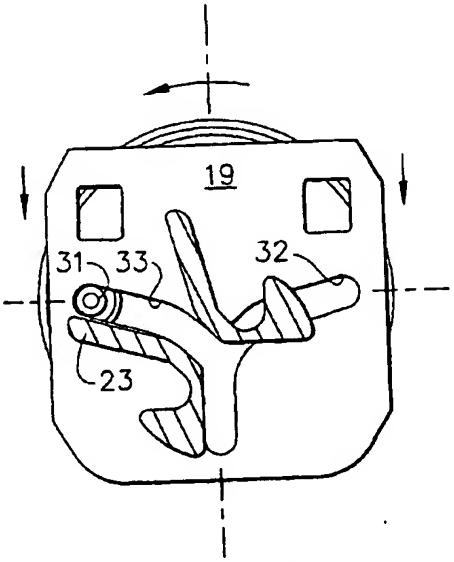

FIG. 13D

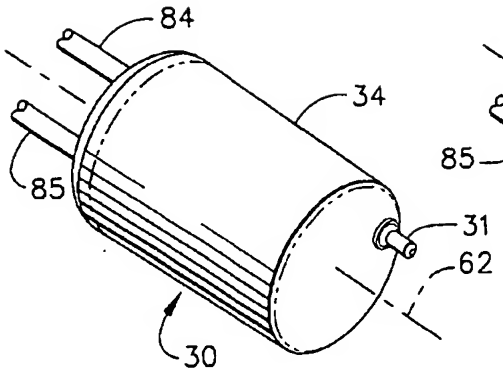

FIG. 14A

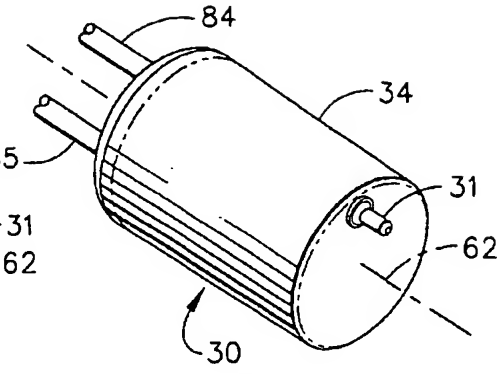

FIG. 14B

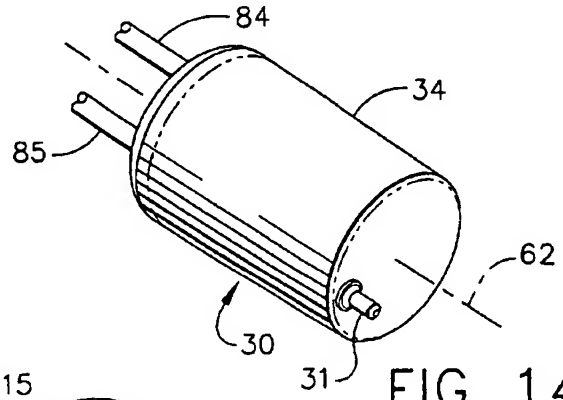

FIG. 14C

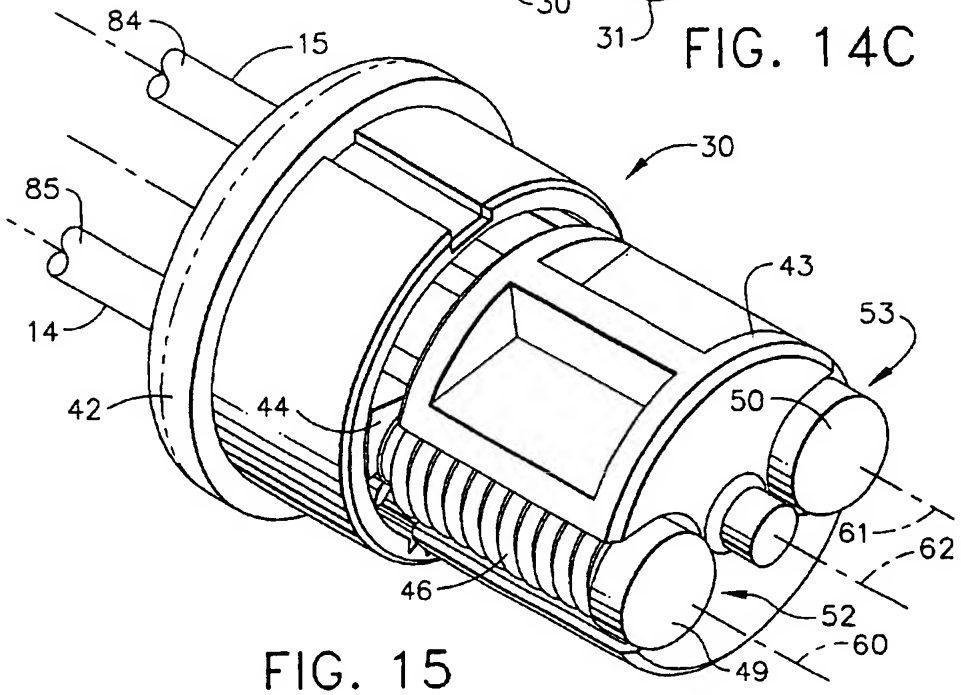

FIG. 15

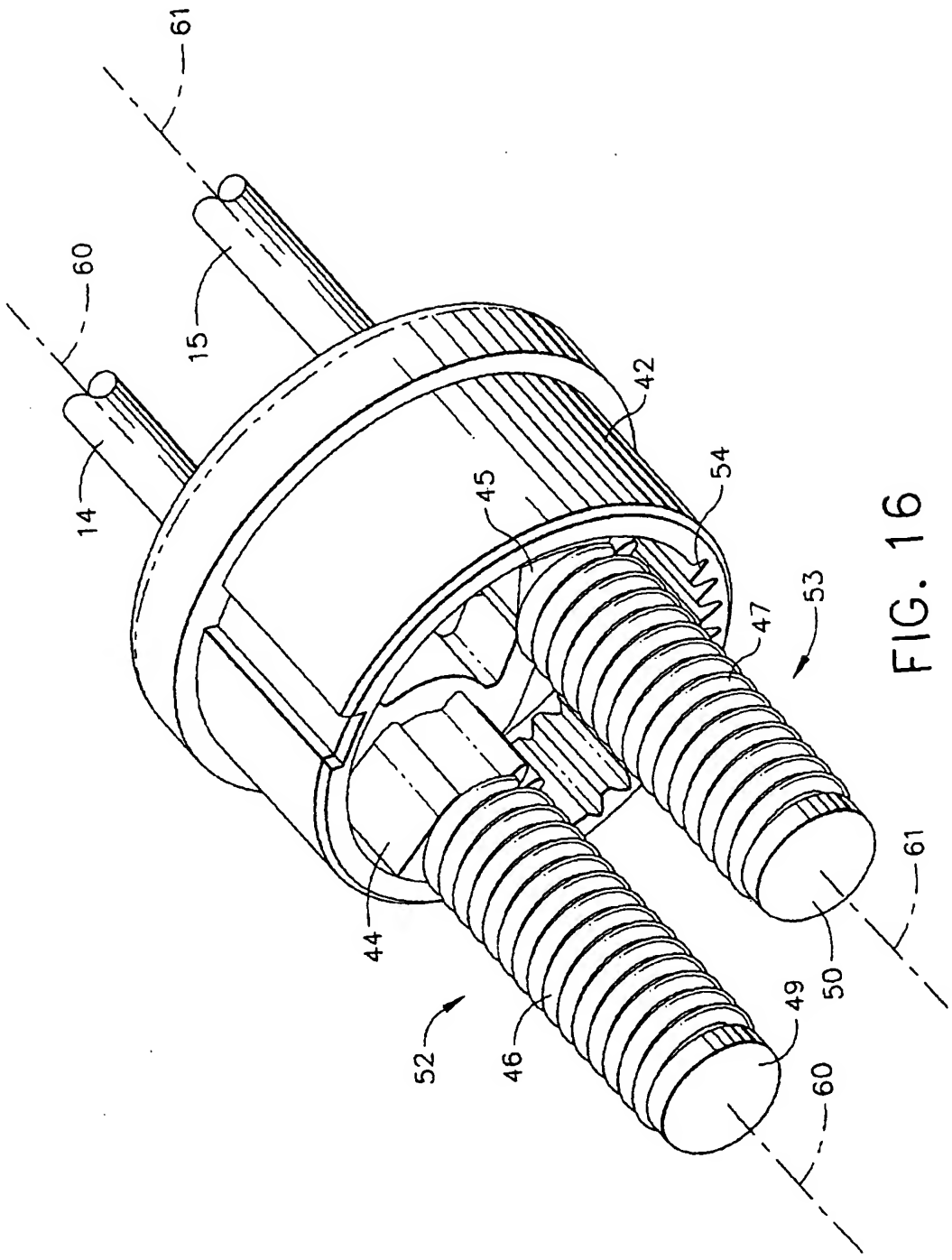

FIG. 16

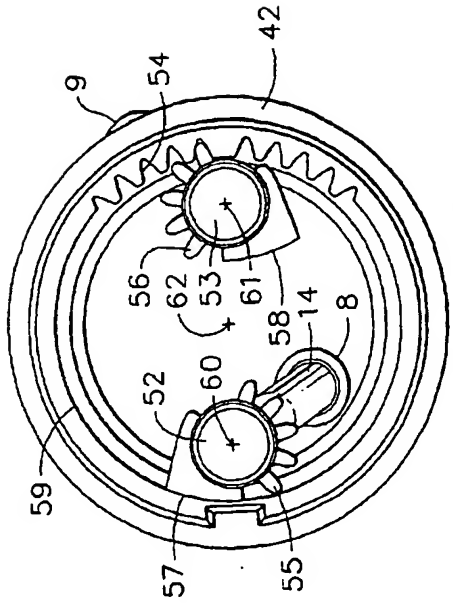

FIG. 17C

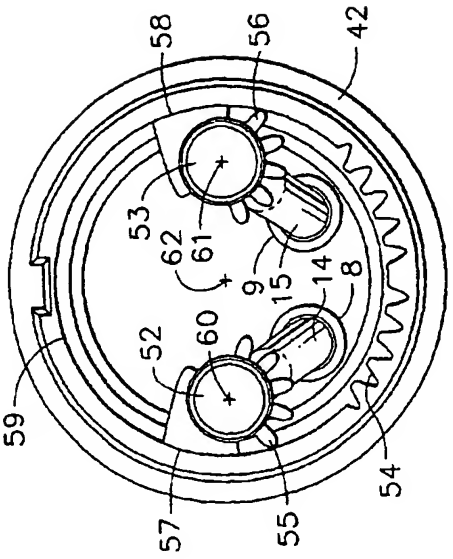

FIG. 17B

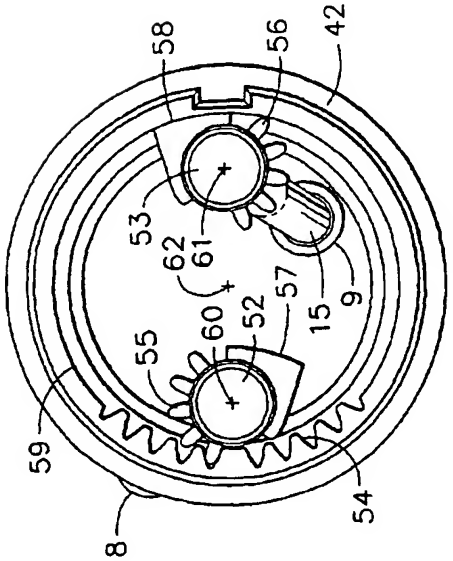

FIG. 17A

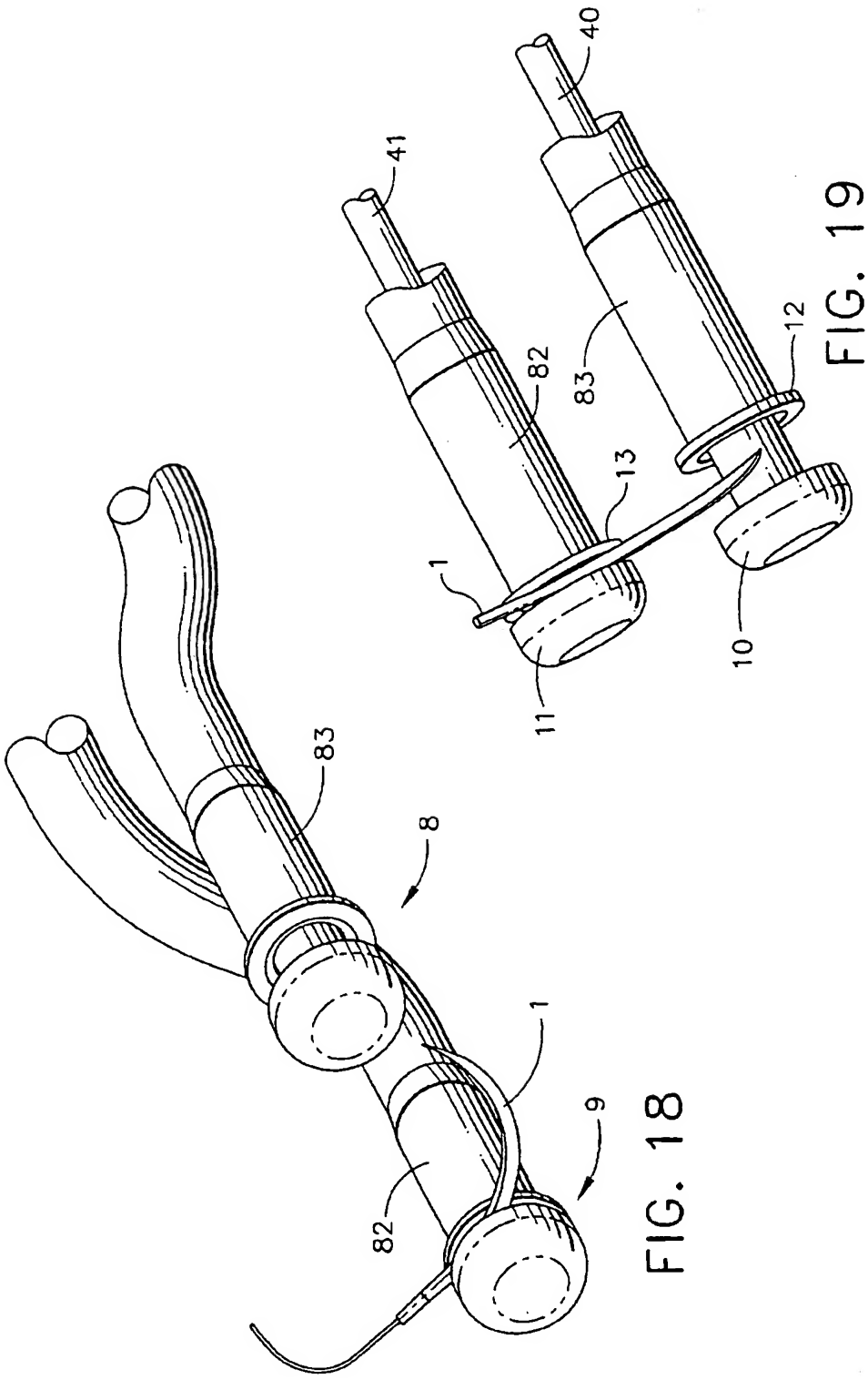

FIG. 19

FIG. 18

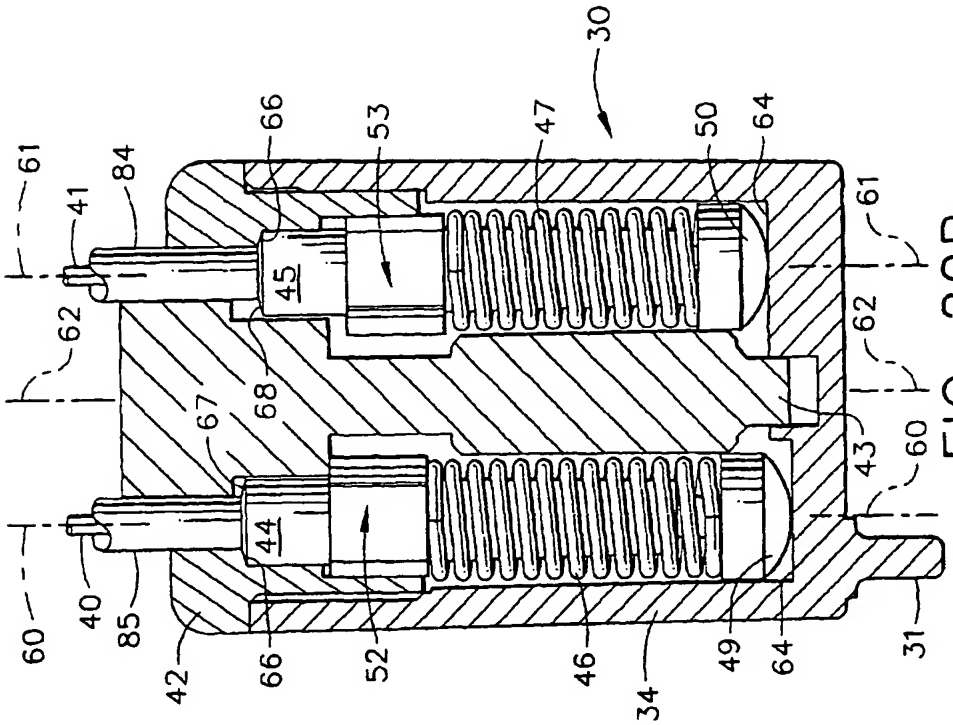

FIG. 20B

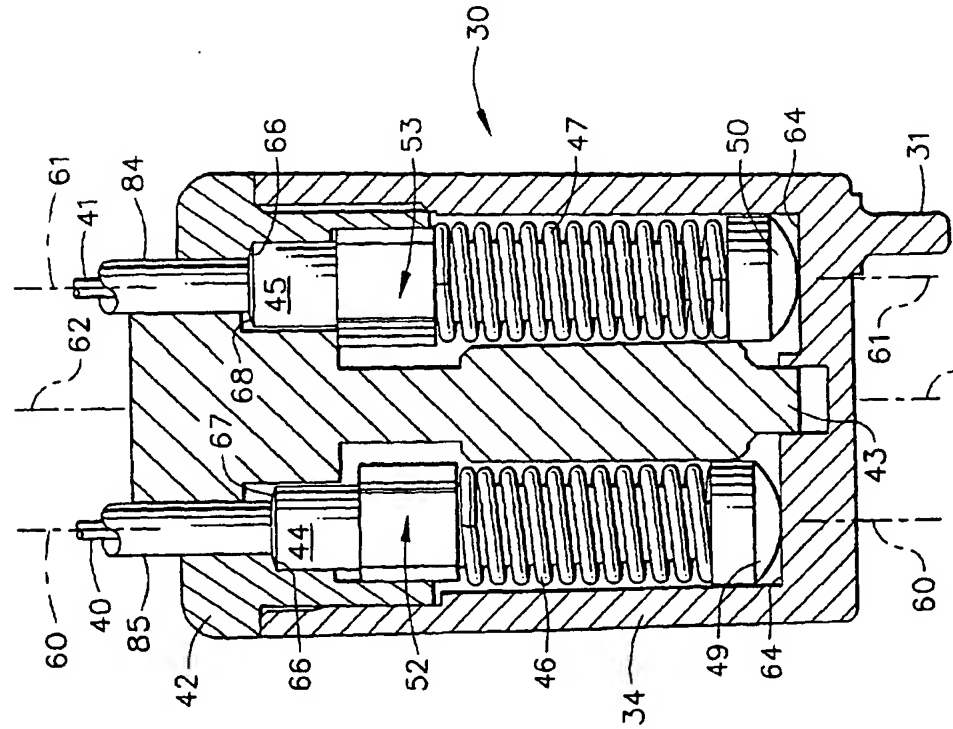

FIG. 20A

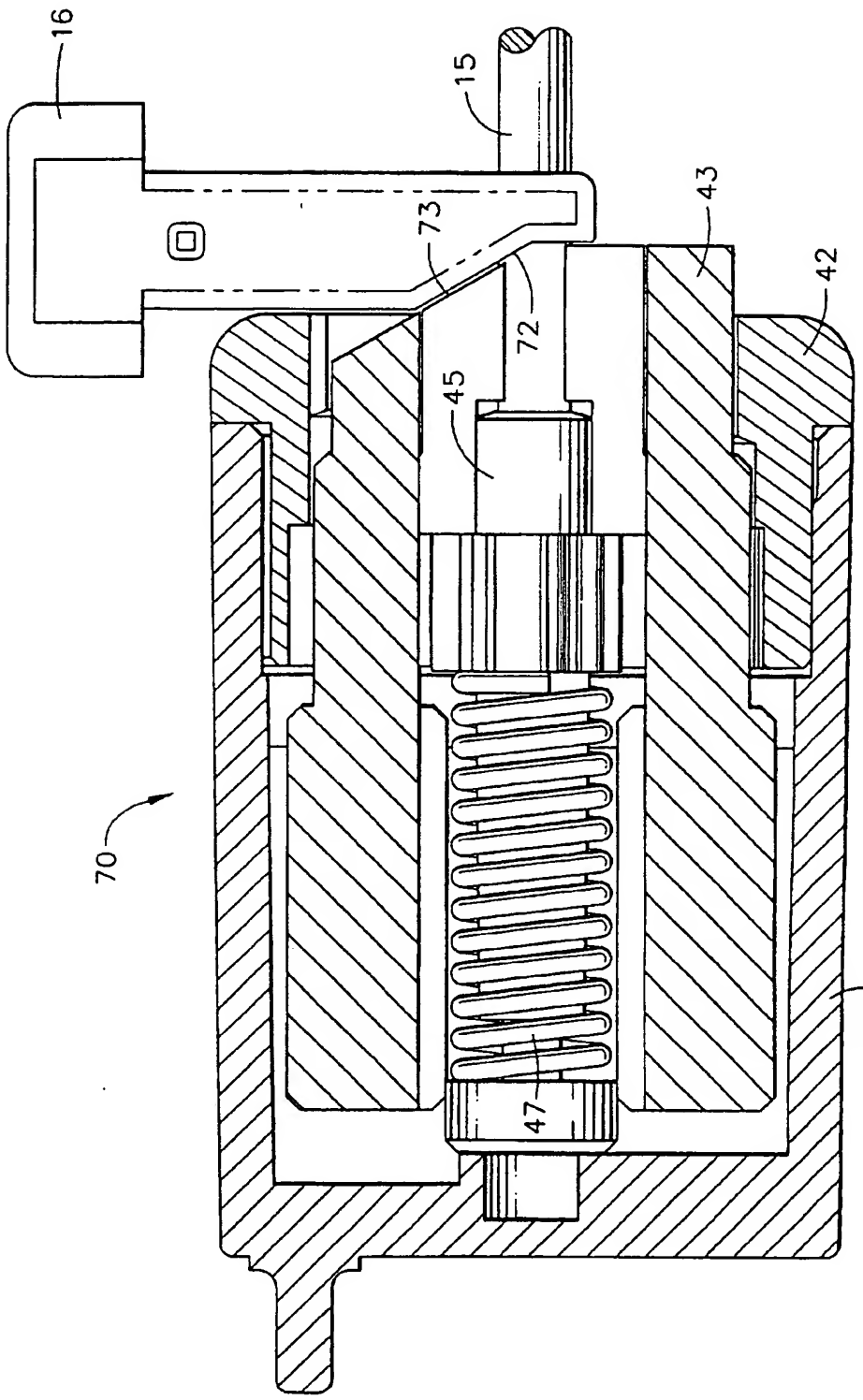

FIG. 21

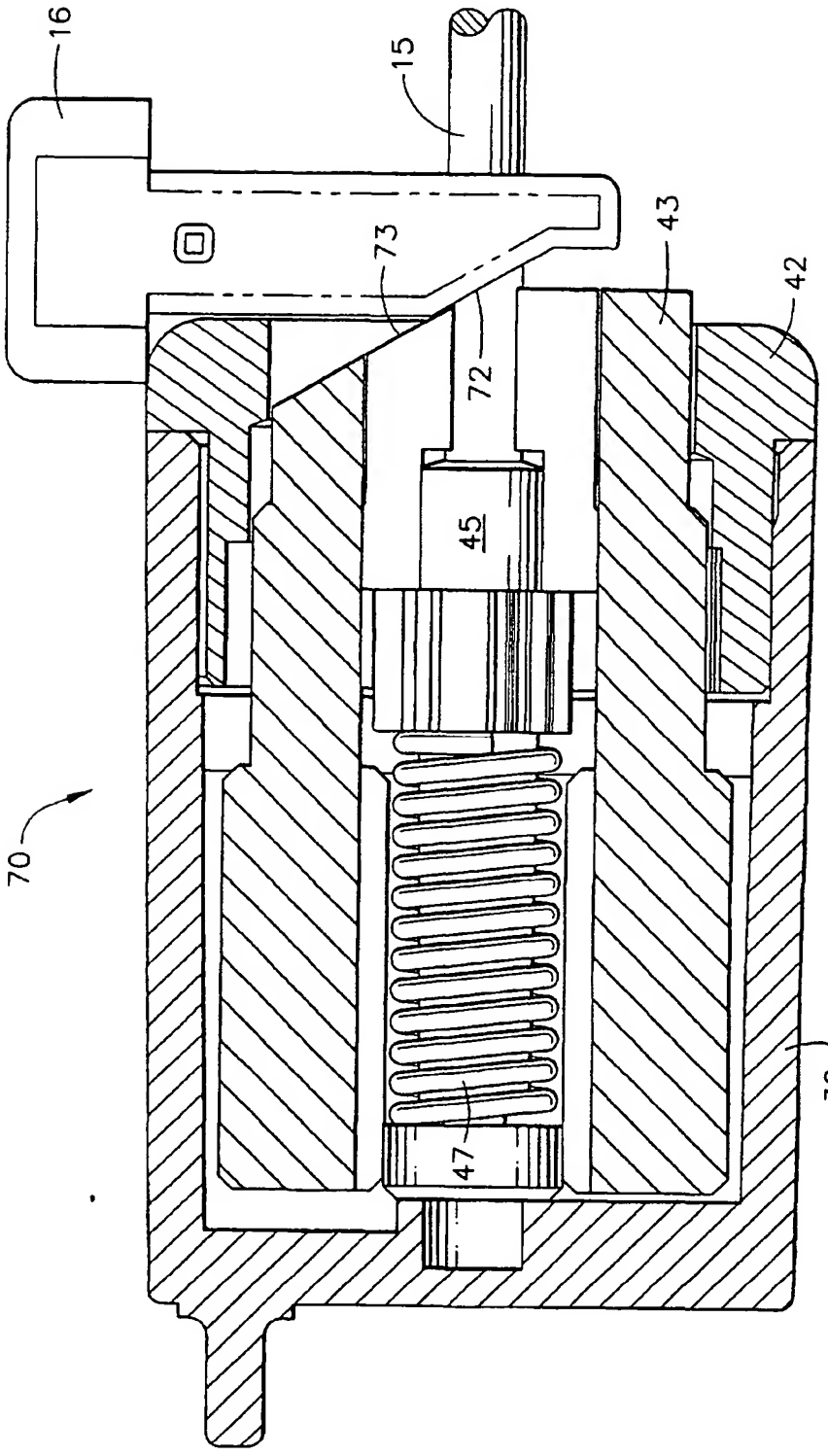

FIG. 22

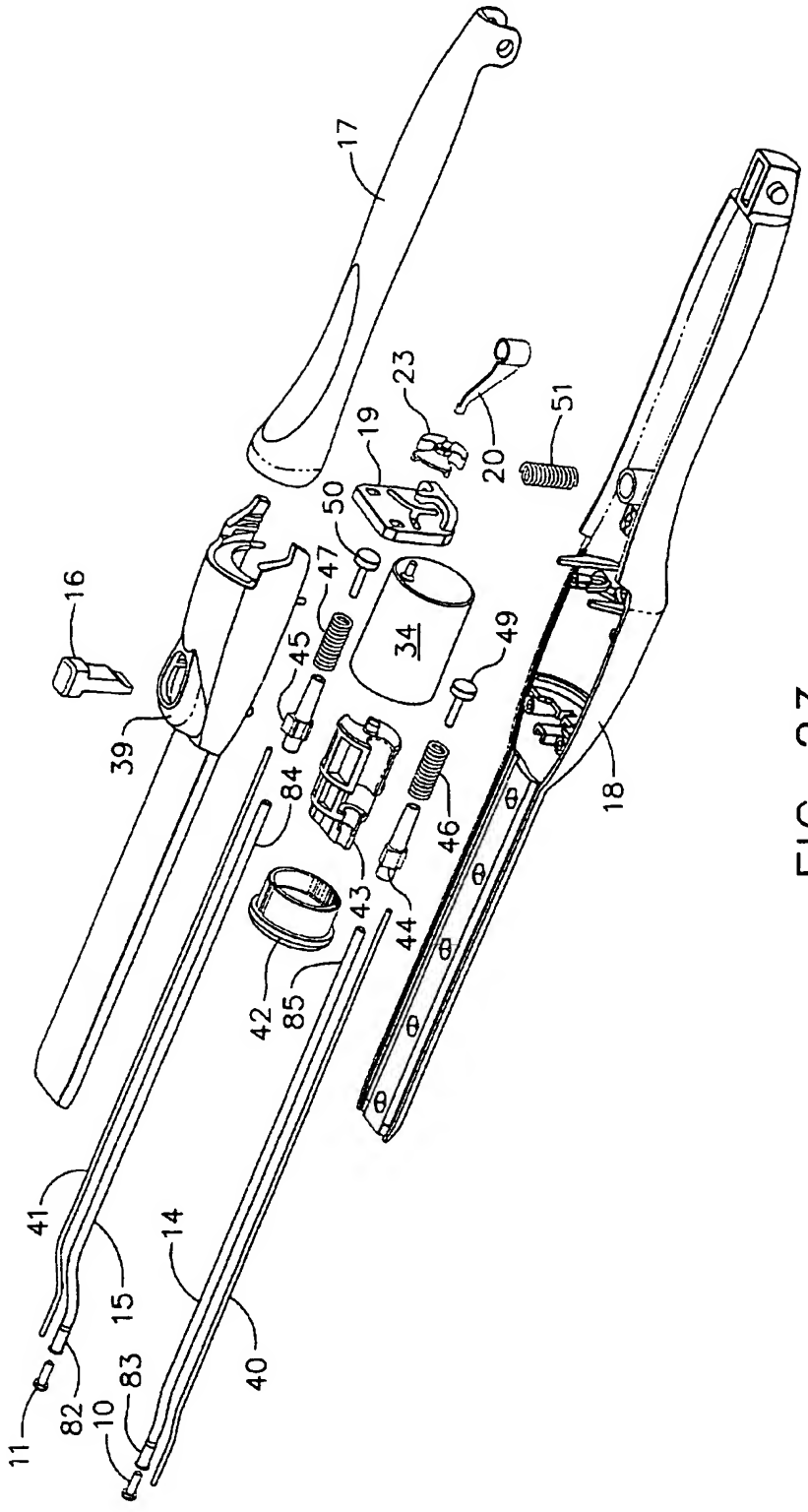
17
23
19
51
20
50
16
47
45
34
49
39
84
46
18
43
44
42
85
41
14
15
40
82
83
10
11

FIG. 23

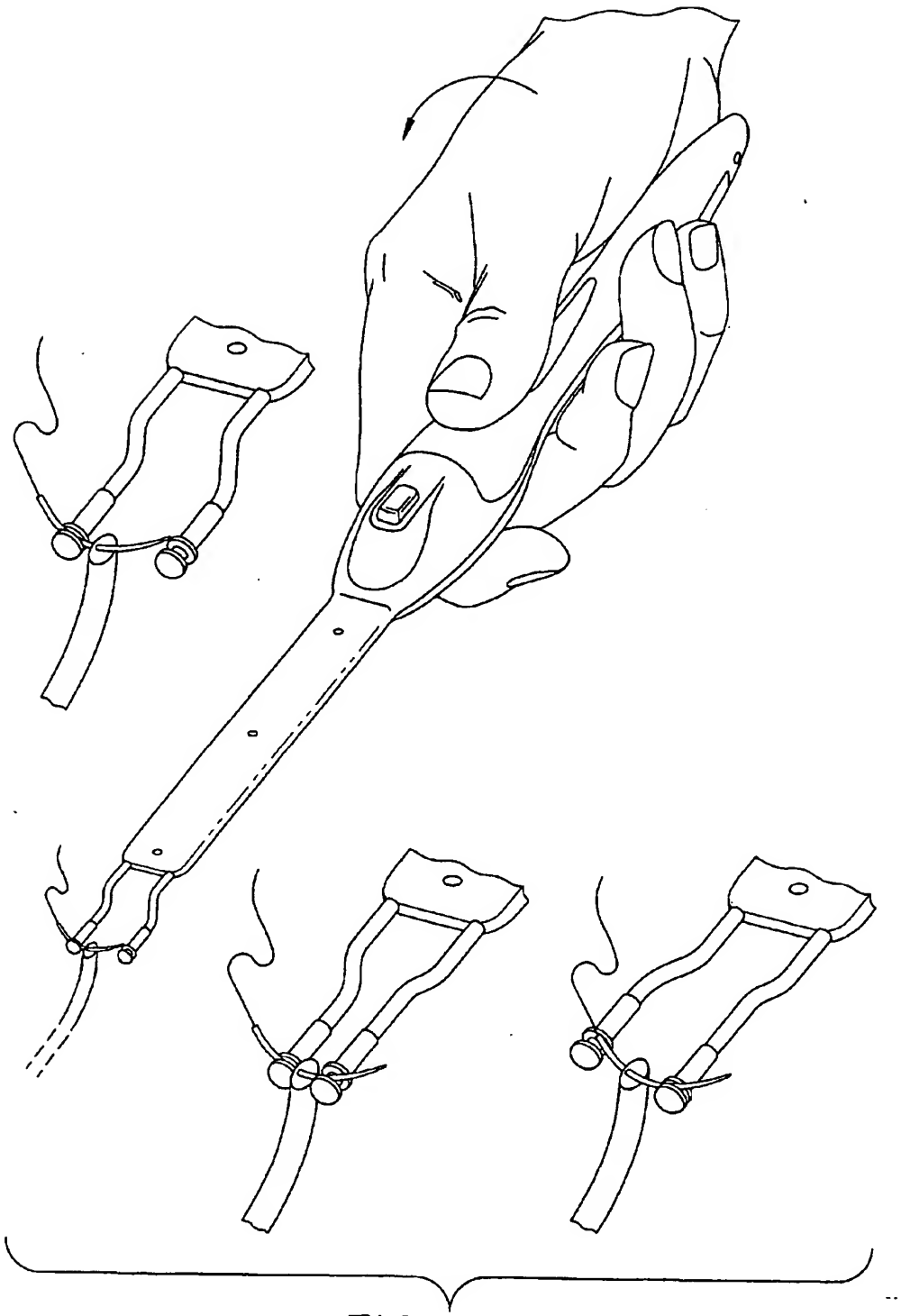

FIG. 24

This Page is Inserted by IFW Indexing and Scanning Operations and is not part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.
As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.